IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	S. Bailey, et al.	Attorney Docket:	6006-009
Serial No.:	09/783,633	Examiner:	C. Miller
Filed:	February 14, 2001	Art Unit:	3738
Confirmation No.:	2694	Customer No.:	29,335

Title: *In Vivo* Sensor and Method of Making Same

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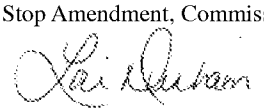

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SUBMISSION OF APPLICANT'S BRIEF ON APPEAL

Dear Sir or Madam:

Applicant submits herewith Applicant's Brief on Appeal. The Commissioner is authorizes to deduct the required fee for filing an Appeal brief in addition to a two month extension fee from Deposit Account 18-2000, of which the undersigned is an authorized user. Accordingly, Applicant does not believe any additional fees are due in the Appeal Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000.

APPEAL BRIEF

1. Real Part in Interest

The real party in interest for this patent application is Advanced Bio Prosthetic Surfaces, LTD., the assignee of the application.

2. Related Appeals and Interferences

The following appeals have either been decided or are pending in patent applications that are commonly owned with the present application. While Applicant does not believe that these pending appeals will directly affect or be directly affected by the Board's decision in the present appeal, Applicant discloses these Board decisions and pending appeals due to the common ownership of the patent applications in question.

Board Decision in present application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216.

Board Decision for related U.S. Application 09/707,685 decided on September 29, 2008, Appeal 2008-1316.

Board Decision for related U.S. Application 10/258,087 decided on December 20, 2008, Appeal No. 2008-1062.

Board Decision for related U.S. Application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212.

Pending Appeal in U.S. Patent Application 09/716,146 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and Method of Manufacture Thereof, filed on November 17, 2000, Appeal No. 2010-7338 (Attorney Docket No. 6006-018).

Pending Appeal in U.S. Application 11/327,795 to Boyle et al., for Endoluminal Stent, Self-Supporting Endoluminal Graft and Methods of Making Same, filed on January 6, 2006 (Attorney Docket No. 6006-200).

Pending Appeal in U.S. Application 09/707,685 to Palmaz et al. for Endoluminal Stent and Self-supporting Endoluminal Graft and Methods of Making Same, filed November 17, 2000 (Attorney Docket No. 6006-015).

No decisions have been rendered by a court or by the Board in any of the aforementioned pending appeals identified pursuant to 37 C.F.R. §41.37(c)(ii)

3. Status of Claims

Claims 1-67, 70 and 79 have been cancelled. Claims 68, 69 and 71-76 are pending and

stand rejected under 35 U.S.C. §102(b), §102(e) and 103(a). Claims 77, 78 and 80-85 are pending and stand rejected under 35 U.S.C. §103(a). The rejections of claims 68, 69, 71-78 and 80-85 are under appeal. Clams 68, 69, 71-71-78 and 80-85 are set forth in their entirety in Claims Appendix identified below.

4. Status of Amendments

No amendments to the claims were filed after the final rejection.

5. Summary of Claimed Subject Matter

Claims 68 and 77 are independent claims in the pending application. Antecedent support for each element in clams 68 and 77 is noted in the parentheses following each claim element:

Claim 68. A system comprising: an in vivo sensor device (page, 16, lines 20-23, page 18, lines 25-29, page 21, lines 21-23) comprising a plurality of structural elements (page 21, lines 23-24, page 23, lines 10-12) defining the in-vivo sensor device (page 21, line 29), the plurality of structural elements including a first region (page 16, lines 24-28, page 18, line 27-page 19, line 4, page 22, lines 6-10) being composed of a first material (page 16, line 26-page 17, line 5, page 19, lines 4-10, page 22, line 29; page 22, lines 1-6), the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state (page 22, line 29; page 22, lines 1-6), the plurality of structural elements including a second region being composed of a second material (page 17, lines 5-16, page 19, lines 4-13, page 22, lines 6-10), the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient (page 22, lines 6-12), wherein the second transition temperature and the second transition coefficient allows for a change in the geometer or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device (page 22, lines 10-12; page 22, lines 26-30; page 23, lines 1-2; page 23, lines 26-28; page 24, lines 1-2), wherein the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature (page 22, lines 18-21; page 23 lines 26-28; page 24, lines 1-2); and a detection mechanism configured to detect the change in the geometry or conformation of the in vivo sensor device (page 18, lines 14-24, page 21, lines 5-14, page 22, lines 21-23), and wherein the second material comprises at least one of a shape memory material and a superelastic material (page 17, lines 18-23, page 19, lines 25-30, page 22, lines 6-10).

Claim 77. A system comprising: an in vivo sensor device (page, 16, lines 20-23, page 18, lines 25-29, page 21, lines 21-23) comprising a plurality of structural elements defining the in-vivo sensor device (page 21, lines 23-26, page 23, lines 10-12), the plurality of structural elements including a first region (page 16, lines 24-28, page 18, line 27-page 19, line 4, page 22, lines 6-10) being composed of a first material (page 16, line 26-page 17, line 5, page 19, lines 4-10, page 22, line 29; page 22, lines 1-6), the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state (page 22, line 29; page 22, lines 1-6), the plurality of structural elements including a second region being composed of a second material (page 17, lines 5-16, page 19, lines 4-13, page 22, lines 6-10), the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient (page 22, lines 6-12), the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device (page 22, lines 10-12; page 22, lines 26-30; page 23, lines 1-2; page 23, lines 26-28; page 24, lines 1-2), wherein the first position is coplanar with the surface of the first region and the first position projects outwardly from the surface of the first region during the second transition temperature (page 8, lines 13-24, page 18, lines 1-11, page 20, lines 6-14, Figures 3 & 4); and a detection mechanism configured to detect the second position of the in vivo sensor device (page 18, lines 14-24, page 21, lines 5-14, page 22, lines 21-23), wherein the second material comprises at least one of a shape memory material and a superelastic material (page 17, lines 18-23, page 19, lines 25-30, page 22, lines 6-10).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 68, 69 and 71-76 are unpatentable under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) over U.S. Patent No. 5,601,593 to *Freitag*. For independent claim 68, the Examiner alleged in the Final Office Action dated March 25, 2010 the following:

> Freitag discloses a sensor device (stent 1, see fig.1 or fig.2) comprising a plurality of structural elements (3, 4, 6-9), the elements including a first region (3 or 6) of a first material having a transitional temperature and coefficient to expand from a first to a second state (col.4, lines 20-22, 30-33), the elements including a second region (4 or 7) of a second material having a higher transitional temperature and coefficient (col.4, lines 22-24, 34-39) which allows for a change in geometry of the second region in the second state upon application of a force to the sensor device, wherein the change in geometry changes the positioning of the second region (4) relative the first region (3) during the higher transition temperature (application of heat above 40C), the first and second

> materials being shape memory or superelastic (nitinol, col.4, lines 20-25). Freitag discloses sensor device's [sic] (stents) are typically endoscopically (col.1, lines 15-20; endoscopes have optical abilities to view proper positioning of the stents in the vessel thus may be considered the detection mechanism). If not inherent that an endoscope (detection mechanism) is present, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an endoscope to ensure the stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Freitag are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent.

Final Office Action dated March 25, 2010, pp. 2-3.

Whether claims 68, 69 and 71-76 are unpatentable under 35 U.S.C. §102(e) or, in the alternative, under 35 U.S.C. §103(a) over U.S. Patent No. 6,406,493 to *Tu et al.* (hereafter Tu). For independent claim 68, the Examiner alleged in the Final Office Action dated March 25, 2010 the following:

> Tu discloses a sensor device (annuloplasty stent, see fig.1; col.4 lines 66-col.5 line 2) comprising a plurality of structural elements (11, 13a-v, 14a-b), the elements including a first region (13) of a first material having a transitional temperature and coefficient to expand from a first to a second state (col.6, lines 42-53), the elements including a second region (14) of a second material having a higher transitional temperature and coefficient (col.6, lines 54-65) which allow for a change in geometry of the second region in the second state upon application of a force (temperature forces open) to the sensor device, wherein the change in geometry changes the positioning of the second region (14) relative the first region (13) during the higher transition temperature (col.6, lines 54-65), the first and second materials being shape memory or superelastic (col.6, lines 9-29). Tu discloses the sensor device (annuloplasty stent) to be used with RF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which typically include imaging means that may be considered the detection mechanism as the application of heat/energy need be correctly positioned within the stent in order to assume proper positioning and expansion. If not inherent that the disclosed heat applicators contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the annuloplasty stent with an imaging means to ensure the annuplasty stent is positioned at the correct location in the vessel needing treatment and ensuring proper expansion has taken place. The superelastic and shape memory materials used by Tu are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Final Office Action dated March 25, 2010, pp. 3-4.

Whether claims 77-78 and 80-85 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 5,591,197 to *Orth et al.* (hereafter Orth) in view of U.S. Patent No. 5,562,641 to *Flomenblit et al.* (hereafter Flomenblit). For independent claims 77, the Examiner alleged in the

Final Office Action dated March 25, 2010 the following:

> Orth discloses a sensor device (stent, see fig.5) comprising a plurality of structural elements (13, 16, 20), the elements including a first region (13) of a first material that expands from a diameter to a second diameter, the elements including a second region (20) of a second material which allow for a change in geometry of the second region, wherein the change in geometry changes the positioning of the second region (20) relative the first region (13), the first and second materials being shape memory or superelastic (col.9, lines 30-32). Orth discloses typical intraluminal delivery systems using guidewires with [sic] typically include imaging means that may be considered the detection mechanism as the imaging need be present to correctly position the stent in the treatment location of the vessel. If not inherent that the disclosed delivery devices contain imaging capabilities (detection mechanism), it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the stent with an imaging means to ensure the stent is properly positioned and expanded. Orth discloses the stent to be made of superelastic or shape memory materials (col.9, lines 29-31), and expanding at different times (fig.5, 6 and corresponding description; uses force by balloon or other means to move the second region instead of temperature) however is silent to mention the different regions to have different transition temperatures/coefficients. Flomenblit teaches in the same field of stents, the use of different transitional temperatures/coefficients at different regions of the stent for better control over the positioning of the stent in the vessel (can control portion by portion; col.6, lines 13-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Orth's piecewise stent (having first and second regions that expand at different times independently) with Flomenblit's teaching of using two different transitional temperatures to expand different portions of a stent at different times, in order to provide a stent with increased control over individual regions during implantation. Orth's second elements (20) would have a first coplanar position after the first elements (13) radially expand and a second projecting position after elements 20 expand.

Final Office Action dated March 25, 2010, pp. 4-6.

Whether claims 77, 78 and 80-85 are unpatentable under 35 U.S.C. §103(a) over Freitag in view of U.S. Patent Application Pub. No. 2007/0255395 to *Pollock et al.* (hereafter Pollock). For independent claim 77, the Examiner alleged in the Final Office Action dated March 25, 2010 the following:

> Freitag discloses a sensor device (stent, see fig.1,2 having first elements 3, 6 and second elements 4,7 with different transitional temperatures), see above. Freitag does not however disclose barbs/hooks on the stent. Pollock teaches in the same field of stents, the use of barbs/hooks (20) on the ends of stents (may be applied to any stent configuration (P0031, P0032) in order to attach the stent to the vessel wall (P0006). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Freitag's stent with Pollack's [sic] teaching of barbs for better securement to the vessel wall. Such a stent meets the limitation of second elements (4, 7- which include barbs) having a higher transitional temperature/coefficient in a first

position is substantially coplanar with the first elements (fig.3 of Pollack [sic], P0028, capable or [sic] deforming to coplanar configuration) and a second position projection outwardly form [sic] the first elements (barbs 20 project outward to penetrate the vessel, see fig.1, 2).

Final Office Action dated March 25, 2010, p. 6.

7. Argument

I. The Examiner's anticipation rejection of claims 68, 69 and 71-76 under 35 U.S.C. §102(b) over *Freitag* is improper and should be withdrawn.

For a prior art reference to anticipate a claim, the prior art reference must teach every element of the claim. *See* MPEP §2131; *see also Richardson v. Suzuki Motor Co.,* 868 F.2d 1226. 1236 (Fed. Cir. 1989) (holding that "[t]he identical invention must be shown in as complete detail as is contained in the…claim." [Emphasis added].); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference").

The Examiner has failed to establish that *Freitag* anticipates the claim because *Freitag* does not teach, expressly or implicitly, (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and (c) the element of a detection mechanism configured to detect the change in the geometry of the in vivo sensor device. Applicant submits that independent claim 68 and claims dependent therefrom, specifically claims 69 and 71-76, are patentable over the prior art cited and of record.

a. Freitag *does not provide for the plurality of structural elements including a first region being composed of a first material and a second region being composed of a second material*

Freitag does not teach or suggest that "the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a first transition coefficient" and "the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature" higher than the first transition temperature, as to render Claim 68 anticipated. Claim 68 requires

that the plurality of structural elements include "a first region being composed of a first material" and "a second region being composed of a second material." The plurality of structural elements themselves require a first region of a first material and a second region of a second material, it is not a first structural element being composed of a first material and a second different structural element being composed of a second material, as the Examiner has misconstrued and applied Freitag. As the Examiner notes, Freitag discloses separate structural wire elements 3, 4, 6-9 and elements 4, 7, as including a first material and second material with a higher transitional temperature. Freitag, throughout its' entire disclosure, includes wholly different structural elements or wires that have a different transitional temperatures, and no where in Freitag does a single wire 3, 4, 6-9 include a first region of a first material with a first transitional temperature and a second region of a second material with a second higher transitional temperature. While Claim 68 includes "a plurality of structural elements", the plurality merely means that there are more than one structural element. Still, each structural element must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material, the second material having a second transition temperature" higher than the first transition temperature. The Examiner's misconstruction of Claim 68 has led to an improper §102 rejection of Claim 68, as Freitag fails to disclose each and every limitation of Claim 68.

b. Freitag *does not provide for the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature*

Freitag does not teach or suggest that "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature," as to render Claim 68 anticipated. Again, Freitag discloses a stent with a support structure 2 composed of different and discrete wires 3 and 4 arranged in a zigzag configuration to form individual rings A, B with different shape memories. Freitag, Col. 4, lines 16-24. As noted above, each structural element of Claim 68 must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material." What follows for Claim 68 is that the "change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature" is on the structural element itself and the change in geometry of the second region is not on a separate or different structural element or

wire as the Examiner presupposes. Freitag includes numerous wires 3, 4, 6-9 that may expand at different temperatures, but no single wire in Freitag includes a first region and a second region, whereby the second region changes position relative to the first region during the second transition temperature. As such, Freitag is inappropriate to render Claim 68 anticipated as failing to disclose each and every limitation.

c. Freitag *does not provide for* ex vivo *detection of the change in geometry of the in vivo sensor.*

An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). MPEP § 2111.01(IV); *see In re Paulson* 30 F.3d 1475, 1480 (Fed. Cir. 1994). Any special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998).

As noted by the Examiner, the only instance in which *Freitag* enables observation of the stent at any time during or after placement of the stent is by use of an endoscope. The Examiner was correct in saying that the optical abilities of an endoscope provide for viewing the proper positioning of the stent. This ability, however, does not provide the functionality required by claim 1. The Applicant, at every point in the application, has described the detection mechanism as described in claim 68 as an *ex vivo* device. The methods employed by the described mechanisms include radiographic imaging, ultrasound imaging, magnetic resonance imaging, and RF imaging. *See* P. 14. line 29 - P. 15, lines 1-2. Every one of these methods has at least one application that is an *ex vivo* procedure. Moreover, the Applicant specifically stated:

> Generally, the inventive endoluminal sensor consists of a sensor which is integral with an implantable endoluminal device, such as [a] stent, and which is configured to respond either mechanically, electronically, electromagnetically, or chemically, to cause a mechanical, electrical, electromechanical or chemical change at the sensor and/or the endoluminal device **which is detectable *ex vivo* using non-invasive detection methodologies such as radiography, ultrasonography, magnetic resonance imaging, or radio frequency detection.**

P. 7, lines 11-16 (emphasis added). This statement demonstrates the Applicant clearly considered the detection mechanism to be an *ex vivo* device, and the strength with which the statement is made requires that the only reasonable interpretation of the detection mechanism of claim 68 be

an *ex vivo* device. The explicitness with which the Applicant stated that the detection mechanisms were to be *ex vivo* devices is more than sufficient to inform a person of skill in the art that *in vivo* devices are not to be included within the scope of detection mechanisms embodied by this invention.

The Examiner has provided only a signal potential detection mechanism from *Freitag*, an endoscope. Endoscopies are *in vivo* by definition, requiring entrance to a body to provide images from within the body. After entering the body, the endoscope would only detect a single state of the stent disclosed in Freitag and not be "configured to detect the change in the geometry or conformation of the in vivo sensor device," as claim 68 requires. Any in vivo detection would merely show an image of the stent, not a change in geometry or conformation of the in vivo sensor device. There are no other detection mechanisms taught or suggested by *Freitag*. As such, *Freitag* does not teach or fairly suggest an *in vivo* sensor that undergoes a transition where that transition is detectable by an *ex vivo* detection mechanism. Therefore, *Freitag* does not teach or suggest every element of claim 68, hence it does not anticipate claim 68. For at least this reason, the Applicant submits that independent claim 68, as well as claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

Moreover, the observational capabilities for the endoscope the Examiner has provided could not provide the sensitivity or the capacity to detect first and second regions that transition from a first state to a second state. Claim 68 is directed to "a plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, wherein the second transition temperature and the second transition coefficient allows for a change in the geometry or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." The application sheds light on the plurality of structural elements and the in vivo sensor device being "in vivo sensor device 30 in the form of an endoluminal stent adapted for non-invasive vascular modeling and imaging and the inventive in vivo sensor device 30 comprises a plurality of structural elements 32, 36 that serve to define walls of the sensor device

30." P. 21, lines. 21-25. The endoscope would not be "configured to detect the change in the geometry or conformation of the in vivo sensor device," as stents are on the order of millimeter in length and diameter.

An endoscope is an instrument used to examine the interior of a hollow organ or cavity of the body and endoscopes are inserted directly into the organ. Nothing in the Examiner's reasoning nor capabilities of the endoscope could be "configured to detect the change in the geometry or conformation of the in vivo sensor device." Any in vivo detection would only detect a single state of the stent in Frietag, if that.

For at least these reasons, the Applicant submits that Claims 68, 69 and 71-76 are patentable over Freitag, for Freitag fails to disclose each and every limitation of independent Claim 68.

II. The Examiner's obviousness rejection of claims 68, 69 and 71-76 under 35 U.S.C §103(a) over *Freitag* is improper and should be withdrawn.

For similar reasons to the argument against the Examiner's §102(b) rejection under *Freitag*, the §103(a) rejection is improper, as claims 68, 69, and 71-76 are distinguishable from and patentable over the prior art cited and of record and for Freitag failing to teach or fairly suggest each and every limitation of independent Claim 68. First, as argued above, *Freitag* does not teach or suggest the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; and the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature. Nothing in Freitag teaches or fairly suggests to one of ordinary skill in the art that the individual wire structural elements include a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, or the second material having a second transition temperature higher than the first transition temperature or the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature. Second, the Examiner's obviousness rejection appears to be related to the detection mechanism discussed by the Examiner. However, Freitag does not teach or fairly suggest to one of ordinary skill in the art (a) an *ex vivo* detection mechanism to detect a change in the geometry or (b) conformation of the sensor device such an *ex vivo* sensor would not have been obvious to one of

ordinary skill in the art at the time the invention was made because the device of *Freitag* was not a sensor as described by the Applicant.

a. Freitag *disclosed only an* in vivo *detection mechanism.*

For the reasons put forth above, claim 68 required the detection mechanism to be *ex vivo*. This requirement was not merely one of preference. The invention of claim 68 is designed to detect clinically significant physiological events. P. 4, lines 22-23. These physiological events include temperature, blood pressure, blood flow shear stress, endothelialization, and arteriosclerosis. *See* P. 8, lines 24-25; P. 9, lines 15-16; P. 9, lines 27-30; P. 10, lines 13-17.

The presence of an *in vivo* device, such as an endoscope as taught by *Freitag*, would necessarily affect and interfere with the operation of a device intended to measure the *in vivo* status of these physiological properties. An *ex vivo* detection mechanism is necessary to measure these physiological properties without affecting them. *Freitag* does not teach or suggest such a detection mechanism. As such, the Examiner has not established a *prima facie* case of obviousness, as she has not established it would have been obvious to modify the device of *Freitag* to include an *ex vivo* detection mechanism.

For at least these reasons, the Applicant submits that independent claim 68, as well as claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

b. *The device in* Freitag *is not a sensor as enabled by Applicant.*

Contrary to the Examiner's assertion, *Freitag* does not disclose a sensor as required by claim 68. The Applicant described the invention as suitable for monitoring clinically significant physiological events. P. 4, lines 22-23. Indeed, the creation of the sensor is explicitly stated to be for sensing specific physiological conditions. P. 5, lines 10-14. Critical to this point is that the sensor is for monitoring *in vivo* conditions; any change in the geometry or conformation of the sensor is a result of changes in conditions of the human subject, not a result of foreign means. Indeed, a device is not a "sensor" if it changes the conditions it is purported to be sensing.

The device in *Freitag* is described as a stent "whose restoring force can be changed after having been placed in the body." This phrase fairly describes the purpose of the invention as a stent that can be expanded and retracted *in vivo*; it is not described as a device for monitoring physiological conditions. Indeed, the Examiner stated in her argument that an endoscope may be used for "ensuring proper expansion had taken place." This belies the improper inference the

Examiner is attempting to read into *Freitag*. As a sensor, the device of claim 68 is not intended for the change in geometry or conformation to occur; it is only to occur pursuant to certain triggering physiological changes. Conversely, in *Freitag*, the changes in geometry and conformation are part of a controlled procedure in which the *in vivo* device can be selectively expanded or contracted, regardless of the physiological conditions surrounding the device, to achieve a desired restorative force. Therefore, the Examiner's characterization of *Freitag* as a sensor is improper.

Accordingly, the Examiner has not demonstrated claim 68 to be obvious under *Freitag*. For at least these reasons, the Applicant submits that independent claim 68, as well as claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

III. The Examiner's anticipation rejection of claims 68, 69 and 71-76 under 35 U.S.C. §102(e) over *Tu et al.* is improper and should be withdrawn.

The Examiner has failed to establish that *Tu* anticipates the claim because *Tu* does not teach, expressly or implicitly, (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and (c) ex vivo detection of the change in geometry of the in vivo sensor. Applicant submits that independent claim 68 and claims dependent therefrom, specifically claims 69 and 71-76, are patentable over the prior art cited and of record.

a. *Tu does not provide for the plurality of structural elements including a first region being composed of a first material and a second region being composed of a second material*

Tu does not teach or suggest that "the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a first transition coefficient" and "the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature" higher than the first transition temperature, as to render Claim 68 anticipated. Claim 68 requires that the plurality of structural elements include "a first region being composed of a first material" and "a second region being composed of a second material". The plurality of structural elements

themselves require a first region of a first material and a second region of a second material, it is not a first structural element being composed of a first material and a second different structural element being composed of a second material, as the Examiner has misconstrued and applied Tu. As the Examiner notes, Tu discloses a plurality of structural elements (circular members 11, stenting elements 13a-b, stenting elements 14a-b), however the stenting element 13 and the stenting element 14 are completely separate and discrete structural elements. Tu, throughout its' entire disclosure, discloses that stenting elements 13 and 14 connect different circular members as to form a first group of circular members with element 13 and a second group of circular members with element 14. Tu, Col. 6, lines 9-41. While Claim 68 includes "a plurality of structural elements," the plurality merely means that there is more than one structural element. Still, each structural element must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material, the second material having a second transition temperature" for Claim 68. Tu, fails to disclose any single structural element 13, 14, or 11 as including a first region of the first material and second region of a second material, whereby the second material has a second transition temperature higher than the first material. The Examiner's misconstruction of Claim 68 has led to an improper §102 rejection of Claim 68 in light of Tu. As such, Tu fails to disclose each and every limitation of Claim 68.

b. *Tu does not provide for the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature*

Tu does not teach or suggest that "the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature," as to render Claim 68 anticipated. Again, Tu discloses stenting elements 13 and 14 connect different circular members as to form a first group of circular members with element 13 and a second group of circular members with element 14. As noted above, each structural element of Claim 68 must include "a first region being composed of a first material having a first transition temperature" and "a second region being composed of a second material" having a second transition temperature higher than the first transition temperature. What follows for Claim 68 is that the "change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature" is on or within the structural element and the change in geometry of the

second region is not on a separate or different structural element or wire as the Examiner presupposes. As such, Tu is inappropriate to render Claim 68 anticipated as fairly to disclose each and every limitation.

c. *Tu does not provide for* ex vivo *detection of the change in geometry of the in vivo sensor.*

Contrary to the Examiner's assertion, *Tu* does not disclose an *in vivo* sensor as required by claim 68. Similar to the argument made above, *Tu* teaches the use of *in vivo* devices that inherently interfere with the physiological conditions surrounding the stent. Indeed, this is their intended purpose; *Tu* teaches devices to convey heat to the stent for the purpose of triggering the change in geometry of the shape-memory material. Col. 3, lines 56-64; Col. 7, lines 52-67; Col. 8, lines 1-7. By intentionally causing the transition that results in the change in geometry or conformation of the device, *Tu* precludes itself from functioning as a sensor; if the detectable change in geometry is intentionally triggered, the device cannot be fairly considered to be monitoring the environment around the device for the triggering condition. Once the device has undergone the detectable transition, even if the triggering condition occurs, the device has already transitioned, thus the device cannot convey the occurrence of the triggering condition.

The Examiner does not appear to recognize the nature of the relationship between the heat conveying mechanisms employed by *Tu* and their effect on the shape-memory material included in the stent. The Examiner artificially, and inaccurately, delineates the heat conveying mechanisms into their heat conveying function and their potential imaging function:

> Tu discloses the sensor device (annuloplasty stent) to be used with TF energy, IR energy, ultrasound, laser, catheter, fiber optics, etc, which typically include imaging means that may be considered the detection mechanism **as the application of heat/energy need be correctly positioned within the stent in order to assume proper positioning and expansion.** …[t]he superelastic and shape memory materials used by Tu are responsive to temperature, flow rate and plaque build up as the material may move elastically by the pumping of blood and force by tissue buildup or tissue attachment to the stent surface.

Final Office Action, P. 3-4 (emphasis added). The Examiner is correct in saying the shape memory materials of *Tu* respond to the listed stimuli. However, the Examiner overlooks that the shape memory materials used in *Tu* have already performed their elastic expansion due to the very means she lists as the detection mechanisms. The Examiner cannot include the detection means she lists without including that such means cause the elastic movement of the shape memory materials; that is what is specifically taught by *Tu*.

As shown above, claim 68 requires the *in vivo* device to be a sensor, which requires it to

convey information upon a triggering condition. The invention of *Tu* does not perform this function, and imputing such a function goes against the instructed use of the *Tu* device. For at least these reasons, the Applicant submits that independent claim 68, as well as claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

IV. The Examiner's obviousness rejection of claims 68, 69 and 71-76 under 35 U.S.C. §103(a) over *Tu et al.* is improper and should be withdrawn.

For essentially the same reasons as stated above for the §102(e) rejection, the Examiner's rejection under §103(a) is improper. In determining the differences between the prior art and the claims, the question under 35 U.S.C. §103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). As shown above, *Tu* does not teach or fairly suggest (a) the plurality of structural elements including a first region being composed of a first material having a first transition temperature and a second region being composed of a second material, the second material having a second transition temperature higher than the first transition temperature; (b) the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and (c) the element of a detection mechanism configured to detect the change in the geometry of the in vivo sensor device. Tu teaches the intentional transition of the device's shape memory material by imparting heat to the device, thereby preventing the device from functioning as a sensor. Any modification of the *Tu* device that does not include the intentional expansion of the shape memory material would be contrary to the teachings of *Tu*, and hence not a valid grounds for a §103(a) rejection. For at least these reasons, the Applicant submits that independent claim 68, as well as claims 69 and 71-76 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

V. The Examiner's obviousness rejection of claims 77, 78 and 80-85 under 35 U.S.C §103(a) over *Orth et al.* in view of *Flomenblit et al.* is improper and should be withdrawn.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. *See* MPEP §2142; *see also In re Rinehart*, 531 F.2d 1048 (CCPA 1976). If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit

evidence of nonobviousness. *Id.* The Examiner must determine whether the claimed invention "as a whole" would have been obvious to one having skill in the art at the time of the invention. *See KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007). The rationale to support a conclusion that the claim would have been obvious is that *all* of the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art (emphasis added). *See* MPEP §2143; *see also KSR*, 550 U.S.

The Examiner has failed to establish that Orth in view of Flomenblit renders claim 77 obvious because: (a) the Examiner failed to establish a *prima facie* case against claim 77; (b) Orth in view of Flomenblit fails to disclose or fairly suggest each and every limitation in Claim 77; and (c) the limitation of the second region, in its second position, projecting from the surface of the first region is not obvious in light of Orth in view of Flomenblit. Applicant submits that independent claim 77 and claims dependent therefrom, specifically claims 78, 80, 81, 82, 83, 84, and 85, are patentable over the prior art cited of record.

a. *The Examiner failed to establish a* prima facie *case against claim 77.*

Claim 77 includes the limitation "the first position [of the second region] is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature." More so, Claim 77 requires that "second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." Underline added. The Examiner has not presented factual support that either *Orth* or *Flomenblit* teach or suggest these limitations, nor that the limitations would be obvious to one of ordinary skill in the art at the time of the invention. Indeed, the Examiner did not mention the limitation at all in her rejection of claim 77 in the Final Office Action. As such, the Examiner's rejection does not consider the Applicant's invention "as a whole." For at least this reason, the Examiner's rejection of claim 77 is improper and claim 77 is patentable over the prior art cited of record.

b. *Orth in view of Flomenblit does not teach or fairly suggest each and every limitation of Claim 77*

First, Orth and Flomenblit do not teach or fairly suggest that the "second region changing from a first position to a second position in the second diametric state upon application of at least

one of an internal force and an external force to the in vivo sensor device," wherein the "first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature." Orth discloses first section 11 and second section 12 that are connected by a plurality of notched connecting members 20, which are designed to buckle or deform during the expansion of the stent, while the notched connecting members 20 deforms with a cut notch 21 to buckle during expansion of the stent in Orth. Orth, Col. 6, lines 45-58. Orth repeatedly mentions that only after the stent has been positioned at the site at which it will be implanted, is it expanded and projecting barbs 22 form during radial expansion. Orth, Col. 7, lines 52-55, Underlined added. In stark contrast, the second region of the Claim 77 changes from a first position to a second position in the second diametric state of the first material, where the first material expands from a first diametric state to a second diametric state. Orth specifically requires the notched connecting members to form the projecting barbs 22 when expansion occurs because connecting members 16 cannot expand to form a tension and opposite compressive force on the connecting member to buckle notch and shortens it length. Orth, Col. 7, lines 25-32. When the Orth stent is in a second diametric state, the connecting members cannot change from its deformed position that is coplanar with the surface of the first region to a second position that projects outwardly from the surface of the first region, because the Orth stent requires expansion to deform or buckle the notched connecting members 20. The connecting members 20 deform only during expansion of the stent from a first diametric state to a second diametric state. And even if one of ordinary skill of the art would take Flomenblit's different transitional temperatures and coefficients at different regions of the stent to control the expansion of the stent, as the Examiner inappropriately alleges, the connecting members 20 would, under a grossly misappropriate conclusion, deform to the projecting barb 22 state when the stent is in the expanded state and therefore have ability to pull or force stent sections 11 and 12 closer together in order to form the shortened notched members when the stent is already in an expanded state or second diametric state. Such a combination would render a stent wholly or partly inoperable. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As such, Orth in view of Flomenblit is insufficient to render Claim 77 obvious as failing to teach or fairly suggest each and every

limitation of Claim 77.

Moreover, Claim 77 requires that "the plurality of structural elements including a first region being composed of a first material" and "the plurality of structural elements including a second region being composed of a second material," where the second region changes from a first position to a second position and where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region. In Claim 77, the plurality of structural elements themselves require a first region and a second region, it is not a first structural element being composed of a first material and a second different structural element being composed of a second material as the Examiner has misconstrued. Orth discloses separate and discrete structural elements, none of which include a first region of a first material and second region of a second material and where the second region changes from a first position to a second position. The Examiner cites cylindrical elements 13 as the first region being composed of a first material for Claim 77 and notched interconnecting elements 20 as the second being composed of a second material for Claim 77. Cylindrical elements 13 and notched interconnecting elements 20 are two separate and distinct structural elements in Orth, none of which include two separate regions of different material and where the second region changes from a first position to a second position. The cylindrical elements 13 comprise a series of peaks 14 and valleys 13 to accommodate differing expansion rates, while the notch connecting members 20 connect the first stent section 11 and the second stent section 12, which are designed to buckle or deform during expansion of the stent. Orth, Col. 6, lines 26-51. The cylindrical element 13 does not include a second region composed of a second material that changes from a first position to a second position where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region of the cylindrical element 13. And notched connecting member 20 does not include a second region composed of a second material that changes from a first position to a second position where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region notched connecting member 20. Even if the Examiner contends that the notch 21 of the notched connecting member is a second region composed of a second material, notch 21 is cut into the notch connecting member and is not coplanar and does not assume a first position that is coplanar with the surface of the first region and the second position projects outwardly from the

surface of the first region when the first region is in a second diametric state. As such, Orth is insufficient to render Claim 77 obvious in view of Flomenblit.

Additionally, the Examiner's motivation for combining Orth with Flomenblit is insufficient and improper. The Examiner argued that Orth's second elements (20) would have a first coplanar position after the first elements (13) radially expand and a second projecting position after elements 20 expand. However, the plurality of notched connecting members 20 in Orth are designed to buckle or deform during expansion of stent 10. Orth, Col. 6, lines 45-50. To accomplish the proper deformation of notched connecting member 20, a notch 21 is cut into notched connecting member 20 to provide a weakened area and to allow deformation to take place at that point. *Id.* The Examiner reasons that the it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Orth's piecewise stent (having first and second regions that expand at different times independently) with Flomenblit's teaching of using two different transitional temperatures to expand different portions of a stent at different times, in order to provide a stent with increased control over individual regions during implantation. This rationale is weak and improper hindsight. Flomenblit uses a band of two-way shape memory alloy of the kind used in accordance with the invention has two transition temperatures: a first transition temperature being above body temperature in which it changes from its soft state into its super-elastic state, and a second temperature, being below body temperature, in which it changes from the super-elastic state into the soft state. Col. 3, lines 2-11. Claim 77 requires that the "first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state" and "the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device." Any first transition temperature for Flomenblit expands the stent for form 14 it has in its super-elastic state, but the temperature is reduced below T_2, the second transition temperature, the diameter of the stent narrows as it assumes its form 16 in said soft state. If any element 20 in Orth would include the second transition temperature, element 20 would be in a soft state and shrink to narrow the distance between the connecting members 16, and not deform to buckle and form a barb as Orth requires. And in the alternative, if the connecting members 16 were in the second transition temperature and in a soft state, the connecting members could be "the second material having a second transition temperature and a second transition coefficient higher than

the first transition temperature and the first transition coefficient" and expand from a first diametric state to a second diametric state. Indeed, element 20 if in the first transition temperature as one would presuppose, the element 20 would not be able to buckle or deform, but would rather shrink and shorten the distance between any connecting struts in Orth's stent.

c. *The limitation of the second region, in its second position, projecting from the surface of the first region is not obvious in light of Orth in view of Flomenblit.*

Foregoing the above, *Orth* and *Flomenblit* does not teach or fairly suggest each and every limitation of Claim 77. *Orth* discloses a stent having a plurality of notched connecting members that buckle when the stent expands. Orth, Col. 6, lines 45-67. The notched connecting members are aptly named, as they are connected to separate first and second sections of the stent at either end. *Id.* As such, the notched connecting members necessarily occupy a space between the first and second sections. *See* Orth, Fig. 1 ref. 20, Fig. 1C ref. 20, Fig. 2 ref. 20, and Fig. 2C ref. 20. *Flomenblit* discloses the use of different transitional temperatures and coefficients at different regions of the stent to control the expansion of the stent. *See* Flomenblit, Col. 6, lines 13-67; *see also* Final Office Action dated March 25, 2010, Page 5.

Taking the teachings of *Orth* and *Flomenblit* together, one of ordinary skill in the art would not have arrived at the claimed invention of claim 77. Claim 77 requires the second position of the second portion to "project outwardly from the surface of the first region." *Orth* explicitly defines the notched connection members 20 as connecting first and second sections 11 and 12 of the stent. The figures identified above depict the notched connecting members 20 disposed between the first and second sections. Critically, Fig. 2C clearly shows the notched connecting members projecting outward from the *plane* of the first section, but not projecting outward *from the surface* of the first section. Requiring that the second region project from the surface of the first region necessarily requires the second region be bound by the projection of the first surface. By definition, the notched interconnecting members cannot be bound by the projection of the surface of a first region; were that so, it could not connect the first and second sections, as is required by *Orth*. As such, one of ordinary skill in the art at the time of the invention would not conceive of the invention of claim 77 in light of *Orth*, as that invention would be contrary to the teachings of *Orth*. For at least these reasons, applicant submits that pending claims 77, 78, and 80-85 are distinguished from and patentable over the prior art cited of record.

Finally, nothing in Orth indicates that the second position of the notched connecting

member 20 would be detected by a detection mechanism. Orth discloses that when the stent is expanded from a low profile, first diameter, the connecting members having a notch will buckle outwardly forming a projecting barb which will penetrate the aortic wall and thereby attach the stent-and-graft combination to the aortic wall. Orth, Col. 4, lines 3-7. Something that attaches to an aortic wall does not show it would be detectable by a detection mechanism. More so, Orth discloses that these projecting barbs may be employed to affix the stent-and-graft combination. Such configuration would also not be detected by any detection mechanism as the Examiner contends. For at least these reasons, the Applicant submits that independent claim 77 and claims dependent therefrom, specifically claims 78, 80, 81, 82, 83, 84, and 85, are patentable over the prior art cited of record.

VI. The Examiner's obviousness rejection of claims 77, 78 and 80-85 under 35 U.S.C. §103(a) over *Freitag* in view of *Pollock et al.* is improper and should be withdrawn.

For essentially the same reasons above for claim 68, the device of *Freitag* does not teach or suggest every element of claim 77. Moreover, the same elements of claim 68 that were not taught by *Freitag*, as stated in the arguments responding to the Examiner's §102(b) and §103(a) rejections, are absent from the combination of *Freitag* and *Pollock*. The Examiner has failed to demonstrate how either *Freitag* or *Pollock* teach or suggest a sensor as required by claim 77 and described by the Applicant, or how either teach or suggest the use of an *ex vivo* detection mechanism. The Examiner has not shown how either the sensor limitation or the *ex vivo* detection mechanism would have been obvious to one having ordinary skill in the art at the time of the invention, in light of the arguments made above. Moreover, the Examiner has failed to (a) show each and every limitation of Claim 77 is fairly suggested in Freitag in view of Pollock; and (b) the Examiner's motivation for combining Freitag in view Pollock in misplaced and in error.

a. *Freitag in view of Pollock does not teach or fairly suggest each and every limitation of Claim 77*

First, Freitag in view of Pollock does not teach or disclose "second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device," wherein the "first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature." Pollack discloses a hook formed with a frame and the hook 20 may be bent away from the frame 22 by using tweezers to force the pointed end 26 of the hook 20 away from the frame 22 and if the hook 20

and frame 22 are formed as part of an endoluminal device, the device may be mounted on a mandel 42 with pins 44 or similar means to force the pointed end 25 of the hook 20 away from the frame 22. Pollack, ¶ [0046]. At no point of Pollack's hook 20 and frame 20 is the second region changing from a first position to a second position in the second diametric state during any second transition temperature. The hook 20 must be bent away from the frame 22 before any endoluminal device is re-expanded to a second diametric state, by either balloon expansion or self-expansion. And more so, any changing from a first position to a second position in Pollack is done ex vivo and mechanically with tweezers or pins. Contrarily, the present Claim 77 is an in vivo sensor device and the second position projects outwardly from the surface of the first region during the second transition temperature. As such, Freitag in view of Pollack is insufficient to render Claim 77 obvious as failing to teach or fairly suggest each and every limitation of Claim 77.

Secondly, Pollack does not teach or suggest that "the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature". Pollack discloses that the hook 20 is bent or curved such that the pointed end 26 extends out of the frame 22, and when the hook 20 is compressed within the bounds or circumference of the frame 22, the pointed end 26 still extends a short distance out from the frame 22 and the elongated member 24 extends a short distance out of the frame 22 in the opposite direction from the pointed end 26. Pollack, ¶¶ [0026]-[0028]. At no point is the hook 20 of Pollack coplanar with the surface of the frame 22 or any intraluminal prosthesis at which the hook 20 is attached. The present application discloses that the first position is coplanar or flush with the surface of the endoluminal device. Present Application, page 8, lines 15-17. Such is not the case with Pollack's hooks 20, as by definition, the hooks 20 are bent or curved such as to secure themselves to corporeal tissue.

Moreover, Claim 77 requires that "the plurality of structural elements including a first region being composed of a first material" and "the plurality of structural elements including a second region being composed of a second material", where the second region changes from a first position to a second position and where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region. In Claim 77, the plurality of structural elements themselves require a first region of a first material and a second region of a second material, it is not a first structural element being composed of a

first material and a second different structural element being composed of a second material, as the Examiner has misconstrued. Any hook 20 or frame 22 of Pollack would not be apart of the first elements 3, 6 and second elements 4, 7 of the stent in Freitag, as the hook and frame 22 are separate and distinct structural elements. Indeed, Pollack shows the hook 20 and frame 22 being attached to an intraluminal prosethesis as a separate structural element in Figure 4. Contrarily, only Freitag's wires 3, 6 are wires of nitinol with a transition temperature and wires 4, 7 are nitinol with a different transition temperature to overlap into rings A and B. Freitag, Col. 4, lines 20-25. Nothing teaches or fairly suggests to one of ordinary skill in the art to compose the hooks 20 or frame 22 of Pollack as any of the wires 3, 4 in Freitag.

b. *Examiner's motivation for combining Freitag in view Pollock in misplaced and in error*

Additionally, the Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Freitag's stent with Pollack's teaching of barbs on the ends of the stent in order to provide a stent with barbs for better securement to the vessel wall. The Examiner reasons that such a stent meets the limitation of second elements (4,7-which include barbs) having a higher transitional temperature/coefficient in a first position is substantially coplanar with the first elements (fig.3 of Pollack, ¶ 0028, capable or deforming to coplanar configuration) and a second position projection outwardly form the first elements (barbs 20 project outward to penetrate the vessel, see fig. 1,2). Final Office Action, page 6, lines 10-17. The Examiner's reasoning is flawed and improper hindsight reconstruction of Applicant's claim 77. The Applicant is assuming the Examiner is combining Pollack's barbs with the wire material 4, 7 from Freitag; however, such wire material 4,7 material would still not maintain a single structural element that includes a first region of a first material and a second region of a second material where the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature, as required by Claim 77. The combination by the Examiner still has the frame 22 and the hook or barb 20 of Pollack as a separate structural element 4, 7 from the wires 3, 6, which are alleged to include the second material, which still remains as a separate structural element. More so, any second position of the hooks or barbs 20 of Pollack are still not coplanar with the first region composed of a first material, as the wires 3, 6, are arranged in a zigzag configuration to form separate rings A, B on the stent; thus wires 4, 7 cannot be coplanar with wires 3, 6 or project outwardly from one

another because they are separate structural elements.

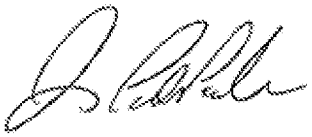
For at least these reasons, the Applicant submits that independent claim 77, as well as claims 78 and 80-85 that depend therefrom, are distinguished from and patentable over the prior art cited and of record.

Conclusion

An anticipation rejection under 35 U.S.C. § 102(b) or §102(e) requires that the cited prior art reference must disclose each and every claimed element. *Freitag* does not teach the use of a detection mechanism as defined by the Applicant, and neither *Freitag* nor *Tu* teach a device that functions as a sensor. The Examiner's characterizations of *Freitag* and *Tu* are contrary to the limitations of the Claims, making them improper bases for §103(a) rejections. *Orth* in light of *Flomenblit* cannot be combined as suggested by the Examiner, hence their combination cannot serve as the basis for a §103(a) rejection. Finally, considering *Freitag* in light of *Pollock* does not overcome the deficiencies of *Freitag*. Thus, each of the Examiner's objections have been shown to be improper, and thus should be withdrawn.

Accordingly, the Applicant respectfully requests the Board withdraw the §102(b), §102(e), and §103(a) rejections of claims 68, 69, and 71-76, and the §103(a) rejections of claims 77, 78 and 80-85, and allow the above-identified application to proceed to allowance and issuance.

Respectfully submitted,



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8. Claims Appendix

The following is a listing of the claims on appeal.

Claims 1-67 (Canceled).

68. (Previously Amended) A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, wherein the second transition temperature and the second transition coefficient allows for a change in the geometry or conformation of the second region in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the change in geometry or conformation changes the positioning of the second region relative to the geometry of the first region during the second transition temperature; and a detection mechanism configured to detect the change in the geometry or conformation of the in vivo sensor device, and wherein the second material comprises at least one of a shape memory material and a superelastic material.

69. (Previously Amended) The system of claim 68, wherein the first material comprises at least one of a shape memory material, a superelastic material, a plastically deformable material, an elastically deformable material, a stainless steel and a nickel-titanium alloy.

70. (Cancelled)

71. (Previously Amended) The system of claim 68, wherein the second material has a martensite transition temperature that is higher than a martensite transition temperature of the first material.

72. (Previously Amended) The system of claim 68, wherein the second material responds to at least one physiological condition.

73. (Previously Presented) The system of claim 72, wherein the physiological condition is fluid flow rate.

74. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is temperature.

75. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is plaque.

76. (Previously Presented) The sensor system of claim 72, wherein the physiological condition is an electrochemical change.

77. (Previously Amended) A system comprising:

an in vivo sensor device comprising a plurality of structural elements defining the in-vivo sensor device, the plurality of structural elements including a first region being composed of a first material, the first material having a first transition temperature and a first transition coefficient to expand from a first diametric state to a second diametric state, the plurality of structural elements including a second region being composed of a second material, the second material having a second transition temperature and a second transition coefficient higher than the first transition temperature and the first transition coefficient, the second region changing from a first position to a second position in the second diametric state upon application of at least one of an internal force and an external force to the in vivo sensor device, wherein the first position is coplanar with the surface of the first region and the second position projects outwardly from the surface of the first region during the second transition temperature; and a detection mechanism configured to detect the second position of the in vivo sensor device, wherein the second material comprises at least one of a shape memory material and a superelastic material.

78. (Previously Presented) The system of claim 77, wherein the first material comprises at least one of a shape memory material, a superelastic material, a plastically deformable material, an elastically deformable material, a stainless steel and a nickel-titanium alloy.

79. (Cancelled)

80. (Previously Presented) The system of claim 77, wherein the second material has a martensite transition temperature that is higher than a martensite transition temperature of the first material.

81. (Previously Presented) The system of claim 77, wherein the second material is configured to respond to at least one physiological condition.

82. (Previously Presented) The system of claim 81, wherein the physiological condition is fluid flow rate.

83. (Previously Presented) The system of claim 81, wherein the physiological condition is temperature.

84. (Previously Presented) The system of claim 81, wherein the physiological condition is plaque.

85. (Previously Presented) The system of claim 81, wherein the physiological condition is an electrochemical change.

9. Evidence Appendix

10. Related Proceedings Appendix

Copies of Board Decision in present application Serial No. 09/783,633 decided on February 21, 2008 in Appeal No. 2008-0216; Board Decision for related U.S. Application Serial No. 09/707,685 decided on September 29, 2008 in Appeal 2008-1316; Board Decision for related U.S. Application Serial No. 10/258,087 decided on December 20, 2008 in Appeal No. 2008-1062; Board Decision for related U.S. Application Serial No. 09/716,146 decided on April 30, 2008 in Appeal No. 2007-3212; and Board Decision for related U.S. Application Serial No. 10/672,695, decided on March 31, 2009 in Appeal No. 2008-5417, are attached herewith.

No decisions have been rendered by a court or by the Board in any of the pending appeals identified under Related Appeals and Interferences pursuant to 37 C.F.R. §41.37(c)(ii).